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(71) Applicant and
(72) Inventor: **FRANTZEN, John, J.** [US/US]; 19 San Rafael Place, Laguna Niguel, CA 92677 (US).

(74) Agent: **HEISLER, Bradley, P.**; Heisler & Associates, Suite 300, 3017 Douglas Boulevard, Roseville, CA 95661 (US).

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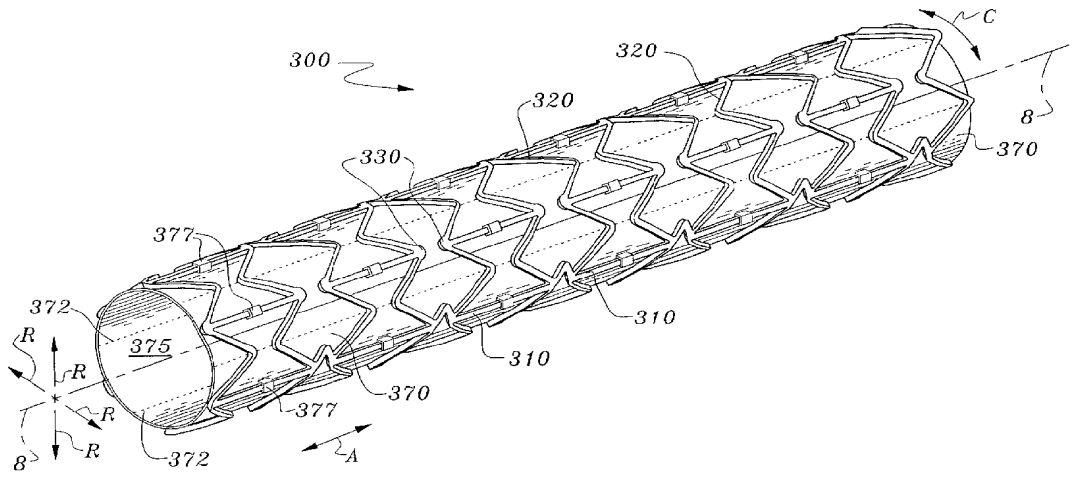
(54) Title: RADIALLY EXPANDABLE STENT FEATURING ANEURYSM COVERING SURFACE



(57) Abstract: A radially expandable stent (300) is provided for blocking necks of aneurysms X in body lumens L such as blood vessels. The stent includes segments (310,320) which extend between junctions (30) and which can have their orientations adjusted to allow the stent to expand radially. A covering surface (370) is provided on at least a portion of the stent. The covering surface is sized sufficiently so that when it is oriented overlying a neck of an aneurysm X blood flow into the aneurysm is blocked and further expansion and/or rupture of the aneurysm X is prevented. The stent can feature a gap which leaves any side pathway of the body lumen L unblocked while positioning the covering surface to block the neck of the aneurysm X.

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RADIALLY EXPANDABLE STENT FEATURING ANEURYSM COVERING SURFACE

Technical Field

The following invention relates to structures which are implantable into body lumens, such as blood vessels to treat aneurysms therein. More particularly, this invention relates to radially expandable stents which include covering surfaces which at least partially block entrances to an aneurysm when the stent is radially expanded with the covering surface adjacent the aneurysm.

Background Art

Aneurysms are bulges in a body lumen such as a blood vessel. Aneurysms are relatively common especially in the larger arteries throughout the body. Aneurysms are related to the absence of a muscular layer that makes up part of the blood vessels, that over time stretches and thins to create the aneurysm. Aneurysms can break resulting in internal bleeding and related complications.

Brain aneurysms are of particular concern because rupture of a brain aneurysm can cause a stroke or death. Studies have shown that between 1% and 5% of the general population have brain aneurysms and that four hundred thousand people in the United States have brain aneurysms of a significant size. While smaller aneurysms (under 6 millimeters) are very unlikely to bleed, approximately thirty thousand people in the United States suffer from an aneurysm rupture every year. It has been estimated that 60% of such ruptures result in death and 20% of such ruptures result in disability. Accordingly, a need exists for effective treatment to reduce the incidence of brain aneurysm rupture.

Known prior art techniques for treatment of aneurysms include direct surgery and endovascular surgery. With direct surgery, the aneurysm is accessed by making incisions in the skin and opening the skull to locate the aneurysm. The neck of the aneurysm is identified where the ballooned aneurysm connects to the blood vessel. Typically the aneurysm is repaired by placing a clip across the neck. Blood flow is then restricted from passing into the aneurysm and continuing to cause ballooning of the aneurysm, which leads to rupture.

With endovascular surgery a catheter enters the body, typically through a leg artery, and is passed up to the location of the aneurysm under x-ray guidance. The aneurysm is then filled to decrease or eliminate blood flow into the aneurysm, which leads to aneurysm rupture. It is known

in the prior art to fill the aneurysm with tiny coils of material or to fill tiny latex or silicone balloons within the aneurysm.

United States Patent No. 5,350,397 is directed to an axially detachable embolic coil assembly which can be discharged from a catheter and used to fill an aneurysm. Other known prior art coil assemblies are disclosed in the following United States patents: 5,217,484; 5,234,437; 5,250,071; 5,261,916; 5,263,964; 5,562,698; 5,578,074; and 5,601,600.

While direct surgery and use of aneurysm clips is generally effective, it requires invasive surgery and the attendant discomfort and risk of complications. While endovascular surgery is less invasive and can more effectively access some blood vessels and other body lumens, the known technique of filling the aneurysm with coils or balloons is not entirely satisfactory. Specifically, when the coils are utilized a risk of displacement exists and the coil can come out of the aneurysm and do damage within the blood vessel, including causing a stroke. The coils are not affixed in any manner within the aneurysm, enhancing this risk. When coils and balloons are utilized to fill the aneurysm, some risk exists that the aneurysm will rupture during the endovascular procedure. For instance, when the coil is released the coil can put sufficient stress on the aneurysm wall to cause the aneurysm to rupture. Similarly, while the balloon is being filled within the aneurysm, it can be overfilled and cause the aneurysm to rupture. Accordingly, a need exists for a new method and apparatus for treatment of aneurysms.

Disclosure of Invention

This invention provides a radially expandable stent which features a covering surface on at least part of the stent for blocking a neck of an aneurysm. The stent is generally cylindrical in structure with segments making up the stent having any of a variety of different configurations as they extend along the cylindrical contour. Preferably, the stent has multiple segments which extend between junctions. When the stent is in its collapsed configuration the segments have significant portions thereof extending close to an axial direction. When the stent is radially expanded significant portions of the segments are reoriented to a less axial orientation and the overall diameter of the stent is increased. Some of the space between the segments can be covered with a flexible covering surface. This flexible covering surface can thus collapse down when the stent is in its collapsed configuration and flexibly unfold to an approximately planar or cylindrical form when the stent is radially expanded.

The covering surface is preferably sized to be at least as large as the neck of the aneurysm and is positioned between a distal end and a proximal end of the stent. Hence, the stent can be radially expanded to securely attach to walls of the blood vessel or other body lumen on both sides of the aneurysm. The covering surface is provided overlying the neck of the aneurysm surface. Blood then flows through an interior of the stent along the blood vessel but is diverted from flow into the

aneurysm by the covering surface.

If the blood vessel includes side pathways near the aneurysm, the stent can be configured so portions thereof adjacent the covering surface are left open to form an unspanned gap. Alternatively, the gap can only be minimally spanned with a small number of elements. Hence, blood flow through the side pathway can occur into a side of the stent with only minimal disruption of blood flow from the side passageway.

The covering surface is preferably formed from a bio-compatible hydrocarbon polymer material forming a layer directly bonded to portions of the stent segments adjacent to the location on the stent where positioning of the covering surface is desired. For instance, if the preferred parylene material is utilized, appropriate vacuum gas vapor deposition techniques can be utilized to form the covering surface. If no side passageways are located near the site of the aneurysm, a stent having all spaces between segments spanned by the covering surface can be provided so that proper positioning of the covering surface over the neck of the aneurysm can more easily occur and/or to treat multiple aneurysms located near each other.

The stent can be formed from plastically deformable metallic alloys, such as bio-compatible stainless steels, or with self-expanding shape memory materials, such as nickel titanium materials. With the use of nickel titanium materials, the stent not only is capable of self expansion within the blood vessel or other body lumen, but also is more able to exert a force against the healthy luminal wall to securely hold the stent in place with the covering surface overlying the neck of the aneurysm.

Brief Description of Drawings

Figure 1 is a front elevation view of a stent of the preferred embodiment of this invention shown as it is being deployed from a delivery tube.

Figure 2 is a cylindrical projection of the stent shown in Figure 1 with additional segments to increase a length of the stent as shown in Figure 2.

Figure 3 is a cylindrical projection of the stent which is shown in Figure 1 with a length of the stent shown in Figure 3 reduced and with a gap adjacent a covering surface of the stent left open.

Figure 4 is a sectional view of a typical blood vessel aneurysm with the stent of the preferred embodiment of this invention implanted therein to block a neck of the aneurysm.

Figure 5 is a cylindrical projection of a first alternative embodiment of that which is shown in Figures 1-4.

Figure 6 is a cylindrical projection of that which is shown in Figure 5 but with the stent shortened and a gap of the stent left open except for the covering surface.

Figure 7 is a sectional view of a blood vessel with an aneurysm and with the stent of Figure 5 deployed therein.

Figure 8 is a cylindrical projection of a second alternative embodiment of the stent of Figure 1, the stent featuring a covering surface filling all spaces between segments of the stent.

Figure 9 is a sectional view of a blood vessel with an aneurysm and including the stent of Figure 8 deployed within the blood vessel to block the neck of the aneurysm.

Best Modes for Carrying Out the Invention

Referring to the drawings, wherein like reference numerals represent like parts throughout the various drawing figures, reference numeral 10 (Figure 1) is directed to a radially expandable stent having a covering surface 70. The covering surface 70 can be located over a neck of an aneurysm X (Figure 4) to divert blood flow D from passing into the aneurysm X and diminish the potential for aneurysm X rupture while remaining portions of the stent 10 hold the covering surface 70 in position.

In essence, and with particular reference to Figures 1-4, basic details of the stent 10 are described. The stent 10 has a generally cylindrical contour made up of a plurality of segments 20 which are joined together at junctions 30. The stent 10 can transition between a collapsed configuration and an expanded configuration having a greater diameter than the collapsed configuration. The stent 10 can thus be delivered intravascularly while within a delivery tube 2 (Figure 1) and then be removed from the delivery tube 2 to expand radially (along arrow R) to engage walls of a body lumen L such as a blood vessel (Figure 4).

A gap 40 can be provided so that blood flow D can pass through the stent 10 from a side pathway of the blood vessel or other body lumen L. Tie bars 50 span the gap 40 and hold distal and proximal portions of the stent 10 on either sides of the gap 40 together. A covering surface 70 spans the gap 40 and is sized to block the neck of the aneurysm X when the stent 10 is in position. Blood flow which would otherwise pass into the aneurysm X abuts the covering surface 70 and remains within the blood vessel as desired.

More specifically, and with particular reference to Figures 1-3, specific details of the stent 10 of the preferred embodiment of this invention are described. The stent 10 exhibits a generally cylindrical form with a plurality of segments 20 extending between junctions 30 to make up the cylindrical form of the stent 10. The cylinder formed by the stent 10 is not walled or enclosed. Rather, the segments 20 and junctions 30 are merely located so that they each lie in a manner which, when they are all considered together, lie along a common cylindrical contour.

Stents have been proposed and manufactured having a variety of different segment and junction configurations. For instance, a single segment can extend helically to form a cylindrical stent. A full discussion of various stent segment patterns is provided in *Handbook of Coronary Stents*, Second Edition. Any of the prior art stents disclosed in that reference or otherwise known in the prior art which exhibit radial expandability could conceivably be adapted for use within the stent 10

of this invention.

For convenience, a stent 10 having a multiple linear segment 20 pattern is provided with junctions 30 between ends of each of the segments 20. The segments 20 are oriented substantially axially (along arrow A of Figure 1) before radial expansion, along arrow R of Figure 1 (see portions of the stent 10 located within the delivery tube 2 of Figure 1). When the stent 10 is radially expanded, along arrow R, the segments 20 transition into an orientation which is less axially aligned and more circumferentially aligned, along arrow C.

Preferably, the stent 10 radially expands to the point where the segments 20 diverge from an axial orientation by 19° when the stent 10 is radially expanded. Preferably, each segment 20 extends approximately 0.1000 inches axially when the stent 10 is radially expanded. Each segment 20 preferably is 0.0020 inches thick. The stent 10 preferably has a compressed diameter of 0.012 inches and an expanded diameter of 0.120. When radially expanded, the length and width of the segments 20, along with the expanded angular deviation from axial orientation of 19° provides the stent 10 with an approximately ten times expansion coefficient. Of course the amount of radial expansion, along arrow R of Figure 1, can be increased by increasing the length of the segments 20 or by increasing an amount of angular displacement of the segments 20 away from the axial orientation when radially expanded.

The segments 20 and junctions 30 which form the stent 10 can be made from a variety of different bio-compatible materials. Preferably however, the segments 20 and junctions 30 of the stent 10 are formed from a shape memory nickel titanium alloy. Such nickel titanium alloys are unique in that they can be treated in a manner which gives the stent a preferred form to which the stent 10 is biased, when a particular temperature, in this case body temperature, is attached. When the stent 10 is cooled to below a transition temperature, the stent 10 becomes much more malleable and can be easily collapsed. When the stent 10 is heated back to its transition temperature, it elastically seeks the form for which it was originally biased. The details associated with the formation and biasing of such shape memory stents are disclosed in detail in United States Patent No. 6,042,606, incorporated herein by reference. Alternatively, the stent 10 can be formed from plastically deformable metal alloys such as stainless steel.

Because aneurysms are enlarged and/or experience rupture due to exposure to blood flow into the aneurysm X (Figure 4) the stent 10 of this invention desirably blocks such blood flow from passing into the aneurysm X. Specifically, the stent 10 includes a covering surface 70 which is preferably sized to be at least as large as a neck of the aneurysm X, defining a portion of the aneurysm X between the healthy wall W of the lumen L and the aneurysm X. The covering surface 70 can have any of a variety of shapes and sizes to match the shape of the neck of the aneurysm X and to otherwise be conveniently supported by structural portions of the stent 10. Figures 1-3 show one form of the stent 10 where the covering surface 70 is configured as a rectangle with axial edges 72 parallel to an axial direction A (Figure 1) and circumferential edges 74 extending circumferentially, along arrow C.

The covering surface 70 can be formed from any of a variety of different flexible materials. To allow the covering surface 70 to be collapsed along with the segments 20 and junctions 30 of the stent 10, it is necessary that the covering surface 70 exhibit flexibility. Most preferably, the covering surface 70 is formed from a parylene film between 0.0001 and 0.002 inches thick, with 0.0005 inches considered ideal.

Parylene is the generic name for members of a family of polymeric di-para-zylylenes. Parylene refers to such thermoplastic polymers that can be formed on surfaces exposed to a rarefied gas in a vacuum. To form the covering surface 70, the parylene can either be deposited onto a mandrel or other deposition surface laying adjacent where the covering surface 70 is to be formed during the vacuum deposition process. Alternatively, a thin flexible base layer can be located where the covering surface 70 is to be formed and then the parylene can be deposited directly onto this base layer to form the parylene covering surface 70. If desired, the entire stent 10, including the segments 20 and junctions 30 can be coated with the parylene that forms the covering surface 70 also.

As an alternative, the covering surface 70 can be formed as a silicone film or from high strength copolymers of silicone and a polycarbonate, such as products marketed under the trademark Chronoflex manufactured by Cardiotech International, Inc. of Woburn, Massachusetts. Other appropriate materials, such as polyesters or polytetrafluoroethylene, or any other appropriate flexible surface materials can be utilized to form the covering surface 70.

With particular reference to Figure 10, additional details of the covering surface 70 and its positioning relative to the stent 10 support structure are described. Figure 10 is a sectional detail taken along lines 10-10 of Figure 8. Figure 8 shows a stent 200 according to an alternative embodiment which is described in detail below. The covering surface 70, 210 is preferably configured with similar cross-sectional characteristics in all embodiment.

While the surface layer 210 can be in a variety of different positions relative to the segments 20 and other structures within the stent 200, the surface layer 210 is preferably configured as shown in Figure 10. Specifically, the covering surface 210 both surrounds the segments 20 and other structural members of the stent 200 and provides a smooth surface, preferably located on an inside surface facing the blood flow D (Figure 9). To achieve this detailed configuration for the surface layer 210, two portions of the surface layer 210 can be provided. First, an outside half layer 212 is provided which surrounds three sides of the segments 20 or other structural element of the stent 200 and spans space between adjacent segments 20. This first outside one half layer 212 is preferably 0.00025 inches thick. A second inside half layer 214 is provided inside of the outside first half layer 212 and surrounds a fourth remaining inner surface of the segments 20 or other structural element of the stent 200. This second inside half layer 214 is preferably 0.00025 inches thick. The second inside half layer 214 includes an inside surface 215 which is entirely smooth and allows blood flow D against the inside surface 215 to occur without any turbulence inducing disruptions. The two half layers 212, 214 together provide the surface layer 210 with a thickness

of 0.0005 inches. While the surface layer 210 attachment to the stent 200 is preferably as shown in Figure 10, other attachment configurations could also be utilized such as with the surface layer 210 medially located between inner and outer surfaces of structural portions of the stent 200 or adjacent the cylindrical outer surface of the stent 200.

The covering surface 70 must be sufficiently flexible so that it does not crack or otherwise break when the stent 10 is in its compressed form within the delivery tube 2. The covering surface 70 must also be sufficiently thin that it does not decrease the ability of the stent 10 to be collapsed into the delivery tube 2. Once the stent 10 is expanded, the covering surface 70 must be sufficiently strong to resist pressure applied to the covering surface 70 due to blood and other fluid flow against the covering surface 70 and other stresses associated with cooling and deploying the stent 10.

The covering surface 70 can be configured within the stent 10 in a variety of different ways. For instance, spaces between adjacent segments 20 of the stent 10 can merely be selected to be filled, either entirely or partially with the covering surface 70. Because spaces between segments 20 of the stent 10 of the preferred embodiment have a somewhat rhomboid pattern, the covering surface 70 will have a configuration similar to that provided by one or more adjacent rhomboid spaces if the covering surface 70 follows the boundaries of the segments 20. For instance, four rhomboid spaces each adjacent a single junction 30 could provide one larger rhomboid space which could be filled with the parylene film or other materials to form the covering surface 70. Similarly, eight rhomboid spaces each adjacent to a ninth central rhomboid space could each be filled with the covering surface 70 for an even larger rhomboid covering surface 70. As another alternative, some of the rhomboid spaces between segments 20 could be only partially filled, such as being half-filled to form triangular portions of a covering surface 70. In such configurations, the segments 20 provide structure to maintain the desired configuration for the covering surface 70.

Preferably however, the covering surface 70 is located within a gap 40 in the stent 10. The gap 40 is positioned between a distal cylindrical structure and a proximal cylindrical structure preferably of similar construction. This gap 40 defines a region where none of the segments 20 and junctions 30 are provided. To keep the two separate cylindrical structures together, tie bars 50 span the gap 40. While a single tie bar 50 spanning the gap 40 could conceivably work, preferably at least three tie bars 50 span the gap 40 (Figure 3). A covering surface 70 is then located adjacent the tie bars 50 with two of the tie bars 50 positioned as perimeter tie bars 52 and with one of the tie bars 50 being an embedded tie bar 54 halfway between the two perimeter tie bars 52. These three tie bars 52, 54 provide structural support to the covering surface 70. Additionally, junctions 30 directly adjacent the covering surface 70 additionally assist in supporting the covering surface 70.

When the gap 40 is provided within the stent 10 and the covering surface 70 is also provided within the gap 40, a particularly common and difficult to treat aneurysm can be blocked. Particularly, and with reference to Figure 4, aneurysms X often form near a branch in a body

lumen L such as a blood vessel. When the blood flows from one branch and is split into two different branches, it will sometimes cause an aneurysm in the wall W directly opposite the side pathway from which the blood or other body fluid D emanates.

It is desirable that the stent 10 both block the neck of the aneurysm X with the covering surface 70 and also leave the side pathway free from obstruction by other portions of the stent 10. When the gap 40 is provided with only the two perimeter tie bars 52 and the one embedded tie bar 54 (Figure 3) the side passageway is left totally open without any obstruction by other portions of the stent 10 (Figure 7). Alternatively, tie bars 50 can be provided spanning the gap 40 and spaced from the covering surface 70 to provide additional support for the stent 10. In such a configuration only two tie bars 50 would potentially cross the junction between the side pathway and other portions of the body lumen L (Figure 4). These two tie bars 50 would be sufficiently spaced apart and of sufficiently small width that they would only minimally disturb flow of body fluids, along arrow D.

Most preferably, the covering surface 70 is planar, rather than curving somewhat cylindrically along with other portions of the stent 10. However, different aneurysms X may benefit from covering surfaces 70 having different contours. Should a covering surface 70 of planar form be desired, bent segments 60 are provided directly adjacent the gap 70 on portions of the gap 70 which are covered by the covering surface 70. Such bent segments 60 preferably include two bends between ends thereof with one end connected to a junction 30 and the other end connected to a circumferential edge 74 of the covering surface 70. The segments 20 which are adjacent to the embedded tie bar 54 are preferably standard segments 20, rather than bent segments 60.

The bent segments 60 are formed so that they have a bias toward being only slightly bent. When the stent 10 is being collapsed into the delivery tube 2, the bent segments 60 are collapsed into a shorter form which allows the covering surface 70 to curve cylindrically. When the stent 10 is removed from the delivery tube 2 and reaches the temperature which causes transition to its radially expanded form, the bent segments 60 elongate somewhat. This elongation causes the axial edges 72 of the covering surface 70 to extend outward from a central axis of the stent 10 slightly. The covering surface 70 thus takes on a planar form.

With particular reference to Figures 1 and 4, details of the use and operation of the stent 10 of the preferred embodiment are described. Initially, the stent 10 has its segments 20 and junctions 30 formed according to the pattern desired to provide the performance desired for the stent 10. While this stent 10 forming process can occur in a variety of ways, it typically involves cutting of the segments 20 and junctions 30 from a cylindrical tube of nickel titanium. This tube is then biased by heat treating the tube appropriately to cause the desired diameter for the tube to be the biased diameter. If necessary, this heating step occurs while the structure of the stent 10 is forced to be expanded or collapsed somewhat from its original diameter before being cut from the tube. After this heat treatment, the stent 10 will be biased toward the diameter which existed when the heat treatment occurred.

Next, the covering surface 70 is applied to the segments 20 and junctions 30 forming the stent 10. The size and position of the covering surface 70 is selected. Either an appropriate supporting substrate or a base film layer is positioned where the covering surface 70 is desired. The stent 10 is then coated with parylene according to known techniques for vacuum deposition of parylene. If desired, all of the segments 20 and junctions 30 of the stent 10 can be coated with the parylene along with formation of the covering surface 70, either against a supporting substrate which is later removed or a flexible film which is coated by the parylene and remains in place.

The stent 10 is then cooled to below a transition temperature so that the stent 10 can be collapsed without plastic deformation of the stent 10. The stent 10 is installed within a delivery tube 2 which has an interior 40 with a diameter similar to a collapsed diameter of the stent 10. The delivery tube 2 is preferably sufficiently flexible to allow it to be passed through arterial pathways within the body and yet sufficiently rigid in a radial direction to resist radial expansion of the stent 10, even if the temperature of the stent 10 exceeds its transition temperature during the implantation procedure.

The stent and delivery tube 2 are then passed through appropriate arterial pathways until the delivery tube 2 and stent 10 are positioned where desired. The delivery tube 2 is then retracted from the stent 10 (Figure 1). As the stent 10 exits from the tip 6 of the delivery tube 2, by retraction of the delivery tube 2 along arrow B (Figure 1), the stent 10 radially expands (along arrow R) to its expanded diameter. The stent 10 is appropriately oriented before full radial expansion so that when the stent 10 is radially expanded the covering surface 70 is precisely where desired for covering of the neck of the aneurysm X (Figure 4). If necessary, a balloon can then be passed through appropriate arterial pathways to an interior of the stent 10 where the balloon can be expanded to ensure that the stent 10 has in fact fully radially expanded.

The stent 10 engages the wall W of the blood vessel or other lumen L with sufficient force to ensure that the stent 10 remains precisely in the desired position with the covering surface 70 overlying the neck of the aneurysm X. Blood flow D attempting to enter the aneurysm X is thus deflected by the covering surface 70 and remains within the body lumen L.

If necessary for proper positioning of the stent 10 and future monitoring, the stent 10 can be configured with radiopaque markers, either at a distal end 12 and proximal end 14 of the stent 10 or adjacent edges of the covering surface 70, or both. Such radiopaque markers can take any known prior art form, including radiopaque marker techniques disclosed in United States Patent No. 5,741,327 and United States Patent No. 6,083,259, incorporated herein by reference. Specifically, materials having greater radiopacity can be attached to appropriate segments 20, junctions 30 or tie bars 50, 52, 54 or certain ones of the segments 20, junctions 30 and/or tie bars 50, 52, 54 can merely be provided with a greater thickness to enhance their radiopacity.

With particular reference to Figures 5-7 details of a first alternative embodiment 100 of the stent 10 is described. The alternative stent 100 is similar to the stent 10 of the preferred embodiment except that no bent segments 60 are provided. Rather, an alternative covering surface 105 is

provided having a first facet 110 non-parallel with a second facet 120. A bend 130 between the first facet 110 and the second facet 120 extends along the embedded tie bar 54. The alternative covering surface 105 thus has a somewhat cylindrical form, as shown in Figure 7. This first alternative embodiment stent 100 is of particular utility in situations where a somewhat cylindrically curved covering surface, such as the alternative covering surface 105, would more effectively block the neck of the aneurysm X.

With particular reference to Figures 8 and 9, details of a second alternative embodiment 200 of the stent 10 are described. The stent 200 of the second alternative embodiment is similar to the stent 10 of the preferred embodiment except that no gap 40, tie bars 50, or bent segment 60 are provided. Rather, part or all of the spaces between adjacent segments 20 are filled with a covering layer so that an alternative covering surface 210 is provided.

In Figures 8 and 9 the alternative covering surface 210 is shown extending all the way from a first edge 202 to a second edge 204 of the stent 200. The stent 200 can be utilized to block aneurysms X' in body lumens L' such as blood vessels which have walls W' which do not have side pathways, but rather are substantially non-branching. For such body lumens L' the gap 40 is not necessary. Such non-branching lumens can include the "triple A" of the aorta, the carotid arteries and many other large and small body lumens. If necessary, in high flow regions, ends 202, 204 can include prongs or other structures extending radially outward to securely hold their position within the lumen L'.

The stent 200 can also be utilized in areas where multiple aneurysms X' exist so that a single stent 200 can treat multiple aneurysms X'. The first alternative embodiment 100 and second alternative embodiment 200 are used in a manner analogous to that disclosed above with respect to the stent 10 of the preferred embodiment.

Where multiple spaces are spanned by the covering surface 210 or where a covering surface 210 is otherwise coupled to segments 20 which are angled away from an axial orientation when radially expanded, distortion of the space and necessarily the covering surface 210 spanning the space must be accounted for. When silicone or other elastic material forms the covering surface 210, the covering surface 210 can stretch and accommodate distortion of the space. When parylene material or other less elastic but flexible material forms the covering surface 210, full coupling of the covering surface 210 to the segments 20 of the stent 200 can lead to covering surface 210 tearing or other damage.

Specifically, when the stent 200 is formed and provided with the covering surface 210 it is typically in an at least partially expanded form. When the stent 200 is later collapsed it elongates axially (along arrow A of Figure 8) and shortens circumferentially (along arrow C of Figure 8). Circumferential shortening is accommodated by folding the covering layer 210. However, axial elongation during collapse can cause the covering layer 210 to stretch beyond an elastic limit of the material forming the covering layer 210. To avoid this, the covering layer 210 can be attached only at selected locations on the stent 200. For instance, the layer 210 can be coupled to the stent

200 at its midpoint between edges 202, 204 but left to slide over segments 20 of the stent 200 elsewhere.

Figures 11-13 show details of a third alternative embodiment where a stent 300 illustrates the selected location covering layer 310 attachment described above. The stent 300 also has axial segments 310 and angled segments 320 joined at junctions 330 in a manner which resists axial elongation when the stent 300 is radially collapsed. In this third embodiment, the stent 300 includes the covering surface 370 similar to that shown in Figure 8 of the second alternative embodiment. The covering surface 370 is cylindrical in form and extends along an entire length of the stent 300. To accommodate radial collapse, opposite arrow R (Figure 11) the covering surface 370 includes fold lines 372. These fold lines 372 identify locations in the covering surface 370 where the covering surface 370 can fold inward when the stent 300 is collapsed radially.

The inner surface 375 of the covering surface 370 is preferably entirely inboard of the segments 310, 320 to provide a smooth surface for blood flow therethrough. The covering surface 370 is attached to the segments forming the structure of the stent 300 at selective locations only. As discussed above, the covering surface 370 can be attached to every segment 310, 320 of the stent 300 if the covering surface 370 is formed from a material having sufficient elasticity to handle the expansion which occurs when the stent is radially collapsed, without exceeding an elastic limit for the material forming the covering surface 370. However, where the covering surface 370 is formed from a material which is not sufficiently elastic, the covering surface 370 is only selectively attached at segment attachment points 377.

As an example, Figure 11 shows the segment attachment points 377 located on axial segments 310. A cross-section of these segment attachment points 377 is similar to the cross-section shown in Figure 10. Because this stent does not elongate or shorten significantly axially (along arrow A) when expanding and collapsing radially (along arrow R) the segment attachment points 377 can be located conveniently on the axial segments 310. Note that the axial segments 310 remain axially aligned, along arrow A, during radial expansion and radial collapse. The angled segments 320 are not attached to the covering surface 370 and so are free to move relative to the adjacent covering surface 370 during radial collapse and radial expansion.

When the stent 300 is being radially collapsed, the covering surface 370 preferably sags inward toward a central axis 8. Such sagging inward can be encouraged by the application of vacuum along an interior of the stent 300 or enhanced pressure along an exterior of the stent 300 or by mechanical force or other means, such that the covering surface 370 folds in a predictable pattern. Where the stent 300 exhibits a large degree of radial expansion, it may be necessary that the covering surface 370 overlap somewhat and extend inward in a spiral manner so that an interior of the collapsed stent 300 remains open. For instance, Figure 13 shows an end view of the stent 300 illustrating one technique for the covering surface 370 to extend inward in a spiral manner when the stent 300 is radially collapsed. Other folding arrangements could similarly be resorted to to allow the covering surface 370 to collapse along with the stent 300.

This disclosure is provided to reveal a preferred embodiment of the invention and a best mode for practicing the invention. Having thus described the invention in this way, it should be apparent that various different modifications can be made to the preferred embodiment without departing from the scope and spirit of this disclosure. When structures are identified as a means to perform a function, the identification is intended to include all structures which can perform the function specified.

Industrial Applicability

This invention exhibits industrial applicability in that it provides a radially expandable stent which includes a covering surface which can be flexibly deployed when the stent is radially expanded to block a neck of an aneurysm, such as a brain aneurysm within a blood vessel.

Another object of the present invention is to provide a stent which can radially collapsed sufficiently to pass through small arterial pathways within a delivery tube, such as arterial pathways leading to brain aneurysm sites, and be radially expanded to a diameter sufficiently large to securely hold position within the blood vessel adjacent the aneurysm.

Another object of the present invention is to provide a radially expandable stent which has spaces between segments at least partially filled with a covering surface.

Another object of the present invention is to provide a stent for treatment of aneurysms which can be implanted without direct surgery and which can be securely held in position adjacent the aneurysm without imparting any damaging stresses upon the aneurysm itself which might cause rupture of the aneurysm.

Another object of the present invention is to provide a stent which can block an aneurysm in a blood vessel with a branching side pathway nearby and not block blood flow in the side pathway.

Other further objects of the present invention will become apparent from a careful reading of the included drawing figures, the claims and detailed description of the invention.

CLAIMS

What is claimed is:

Claim 1 - A radially expandable stent comprising in combination:

a distal cylindrical structure;

a proximal cylindrical structure;

both said distal cylindrical structure and said proximal cylindrical structure having at least two configurations including a collapsed configuration and an expanded configuration, said expanded configuration having a greater diameter than said collapsed configuration;

a gap between said distal cylindrical structure and said proximal cylindrical structure; and

a flexible covering surface located within said gap.

Claim 2 - The stent of Claim 1 wherein said covering surface is connected to both said distal cylindrical structure and said proximal cylindrical structure.

Claim 3 - The stent of Claim 1 wherein said covering surface has a size at least as large as an entrance of an aneurysm.

Claim 4 - The stent of Claim 1 wherein said covering surface only partially fills said gap between said proximal cylindrical structure and said distal cylindrical structure.

Claim 5 - The stent of Claim 1 wherein said covering surface includes a bio-compatible hydrocarbon polymer material having sufficient flexibility to allow said covering surface to flex between a collapsed configuration and an expanded configuration corresponding with said at least two configurations of said distal cylindrical structure and said proximal cylindrical structure of said stent.

Claim 6 - The stent of Claim 5 wherein said covering surface is at least partially formed from parylene.

Claim 7 - The stent of Claim 5 wherein said covering surface is at least partially formed from a silicon film.

Claim 8 - The stent of Claim 5 wherein said covering surface is at least partially formed from a copolymer including both silicone and a polycarbonate material.

Claim 9 - The stent of Claim 1 wherein said gap is spanned by at least one tie bar element.

Claim 10 - The stent of Claim 9 wherein said tie bar element is substantially rigid, such that said tie bar element maintains a width of said gap.

Claim 11 - The stent of Claim 9 wherein said tie bar element is located adjacent said covering surface.

Claim 12 - The stent of Claim 11 wherein at least two of said tie bars span said gap, each of said at least two tie bars oriented axially within said stent; and

wherein said covering surface extends between said at least two axially oriented tie bars.

Claim 13 - A radially expandable stent, comprising in combination:

a plurality of stent segments joined together at a plurality of junctions, said stent segments together generally forming a cylinder;

said stent segments having sufficient flexibility to transition between at least two configurations including a collapsed configuration and an expanded configuration, said expanded configuration giving said stent a greater diameter than said collapsed configuration; and

at least one space between at least two of said plurality of stent segments at least partially filled with a flexible covering surface.

Claim 14 - The stent of Claim 13 wherein said covering surface is coextensive with said cylinder formed by said stent segments, such that said cylinder is at least partially walled by said covering surface.

Claim 15 - The stent of Claim 13 wherein said covering surface has a size at least as large as an entrance to an aneurysm.

Claim 16 - The stent of Claim 13 wherein said covering surface has a size sufficient to cover a majority of said cylinder formed by said stent segments.

Claim 17 - The stent of Claim 13 wherein said covering surface includes a bio-compatible hydrocarbon polymer material having sufficient flexibility to allow said covering surface to flex between a collapsed configuration and an expanded configuration corresponding with said at least two configurations of said stent.

Claim 18 - The stent of Claim 13 wherein said covering surface is at least partially formed from parylene.

Claim 19 - The stent of Claim 13 wherein said plurality of stent segments are formed from a shape memory material biased to prefer said expanded configuration.

Claim 20 - The stent of Claim 19 wherein said stent segments are formed from a material including nickel and titanium therein.

Claim 21 - A radially expandable stent comprising in combination:

at least one stent segment following a contour of a cylinder;

said stent segment having sufficient flexibility to transition between at least two configurations including a collapsed configuration and an expanded configuration, said expanded configuration giving said stent a greater diameter than said collapsed configuration;

space adjacent to a portion of said at least one stent segment at least partially filled with a flexible covering surface; and

said covering surface attached to said stent segment.

Claim 22 - The stent of Claim 21 wherein said at least one stent segment includes an inside surface at least partially facing a centerline of said stent and an outside surface at least partially facing away from said centerline of said stent, material forming said covering surface extending over at least a portion of said outer surface.

Claim 23 - The stent of Claim 22 wherein said covering surface has an inside surface at least as close to a centerline of said stent as said inside surface of said at least one segment.

Claim 24 - The stent of Claim 23 wherein said covering surface surrounds both said inside surface and said outside surface of at least a portion of said at least one segment.

Claim 25 - The stent of Claim 22 wherein said covering surface is attached to at least one segment at multiple attachment locations on said stent and free from attachment to said at least one segment at other locations on said stent.

Claim 26 - The stent of Claim 25 wherein said attachment locations are located at places on said stent which avoid expansion away from each other when said stent is contracted between said expanded configuration and said collapsed configuration.

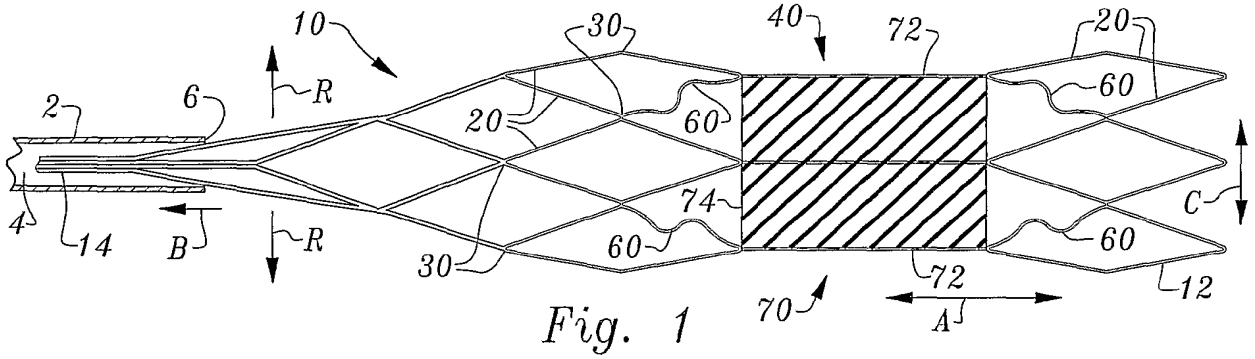

Fig. 1

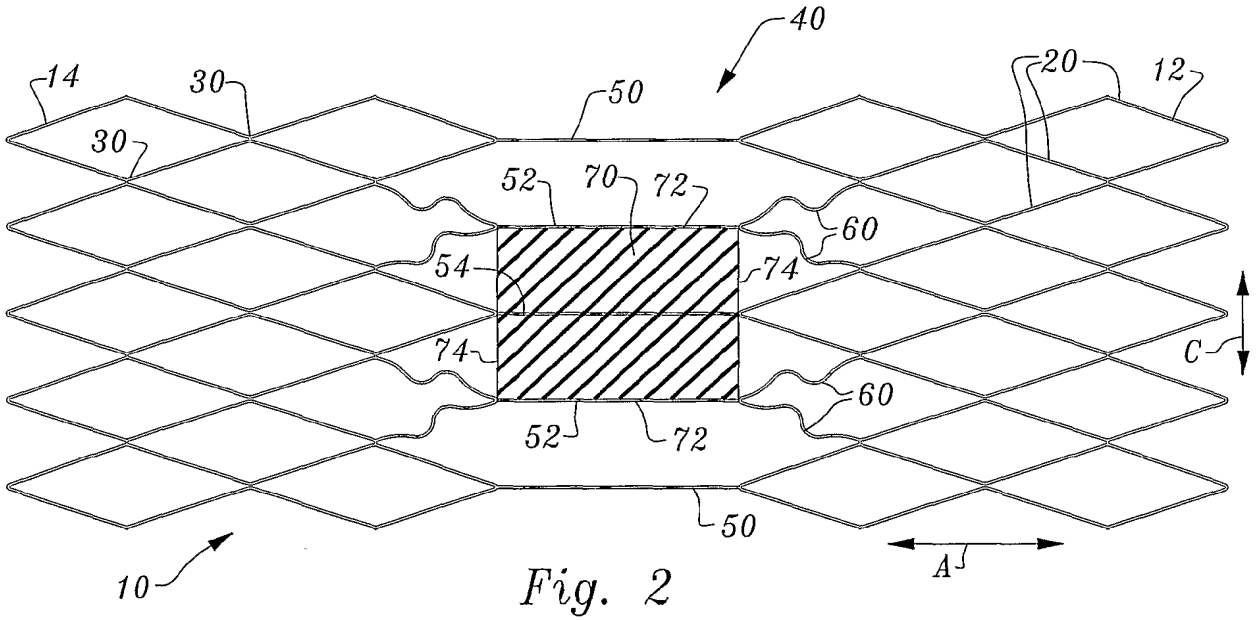

Fig. 2

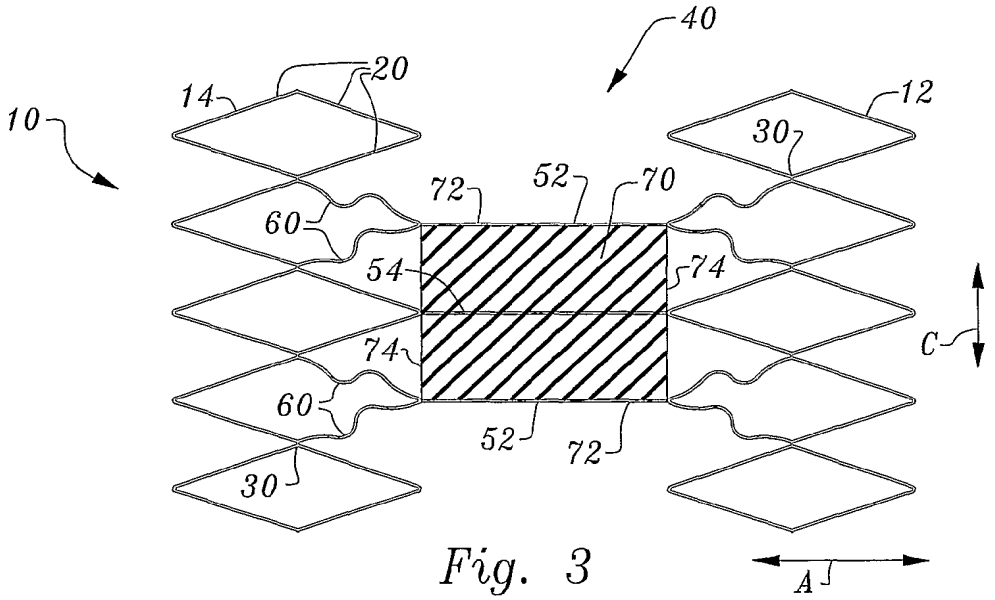

Fig. 3

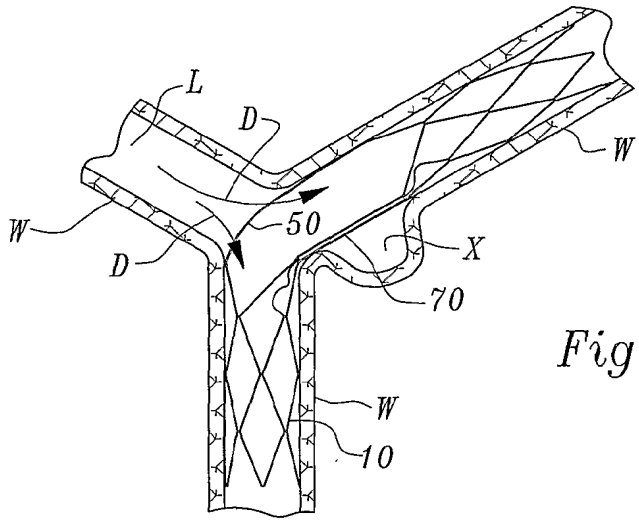

Fig. 4

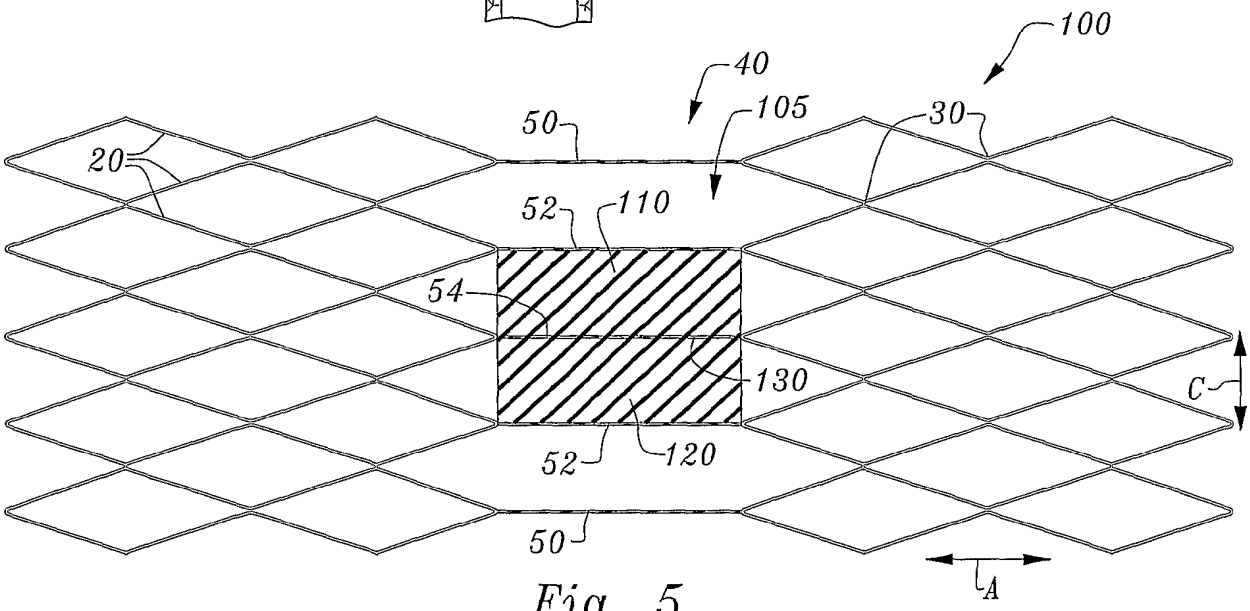

Fig. 5

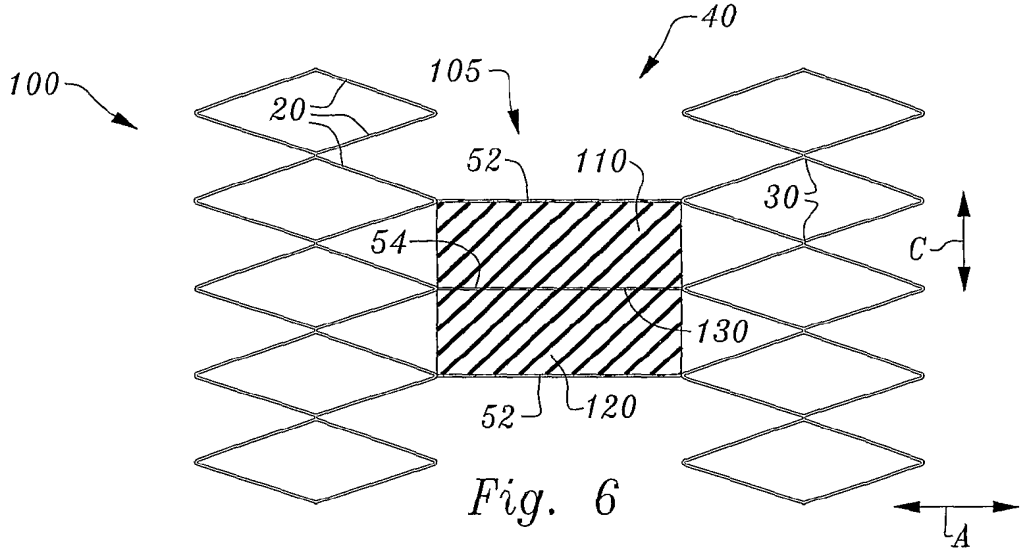

Fig. 6

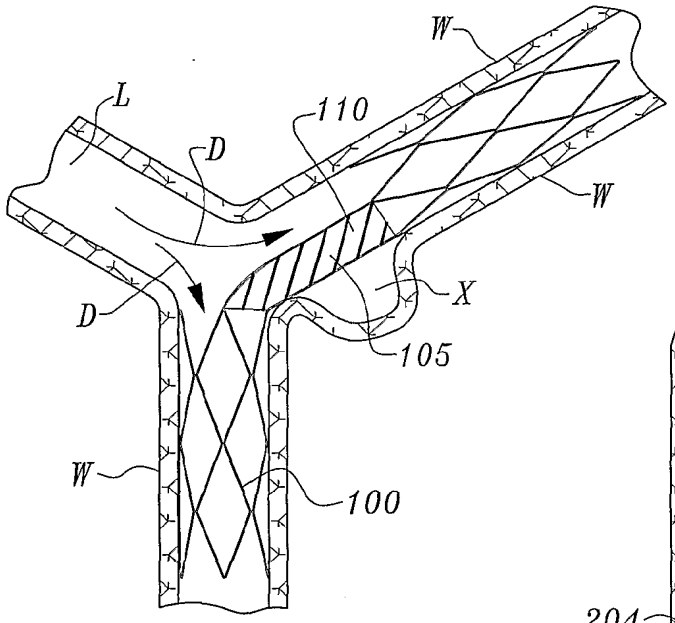

Fig. 7

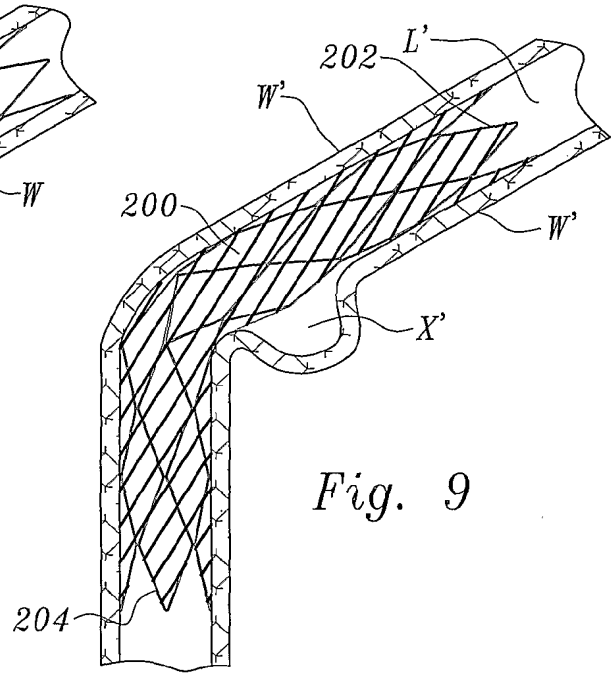

Fig. 9

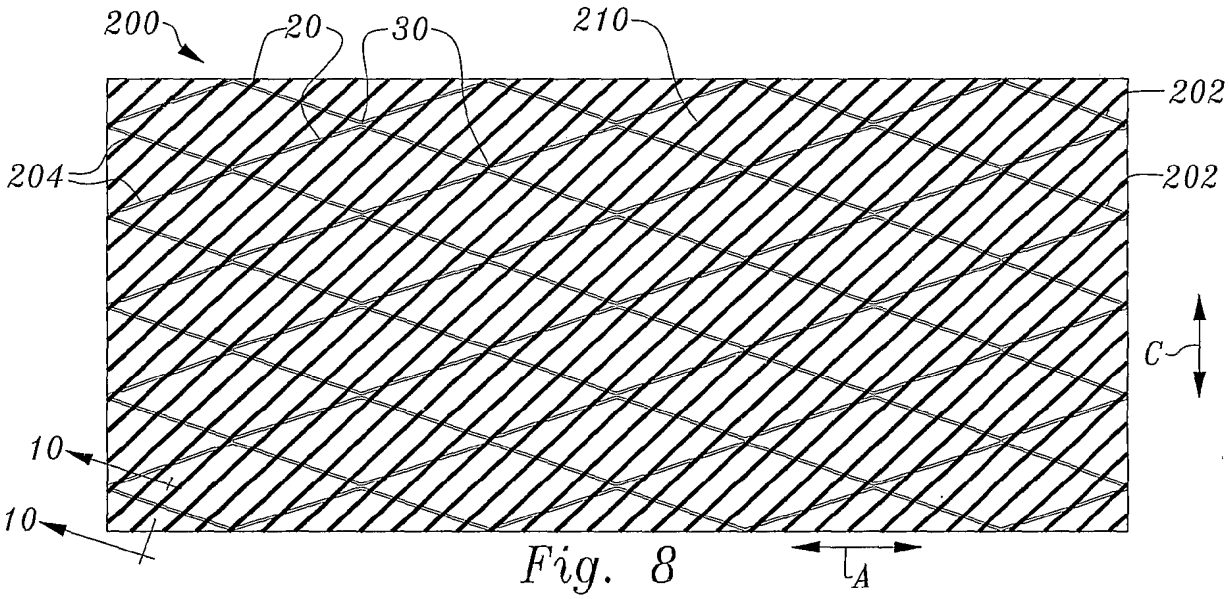

Fig. 8

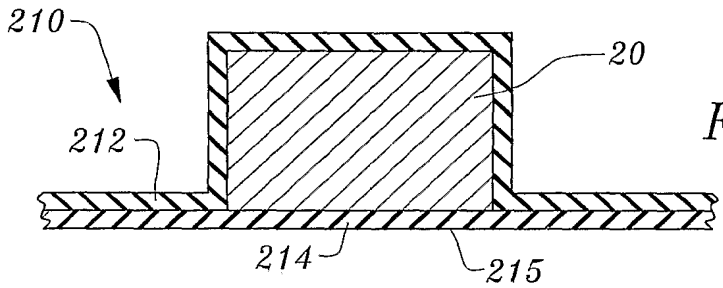

Fig. 10

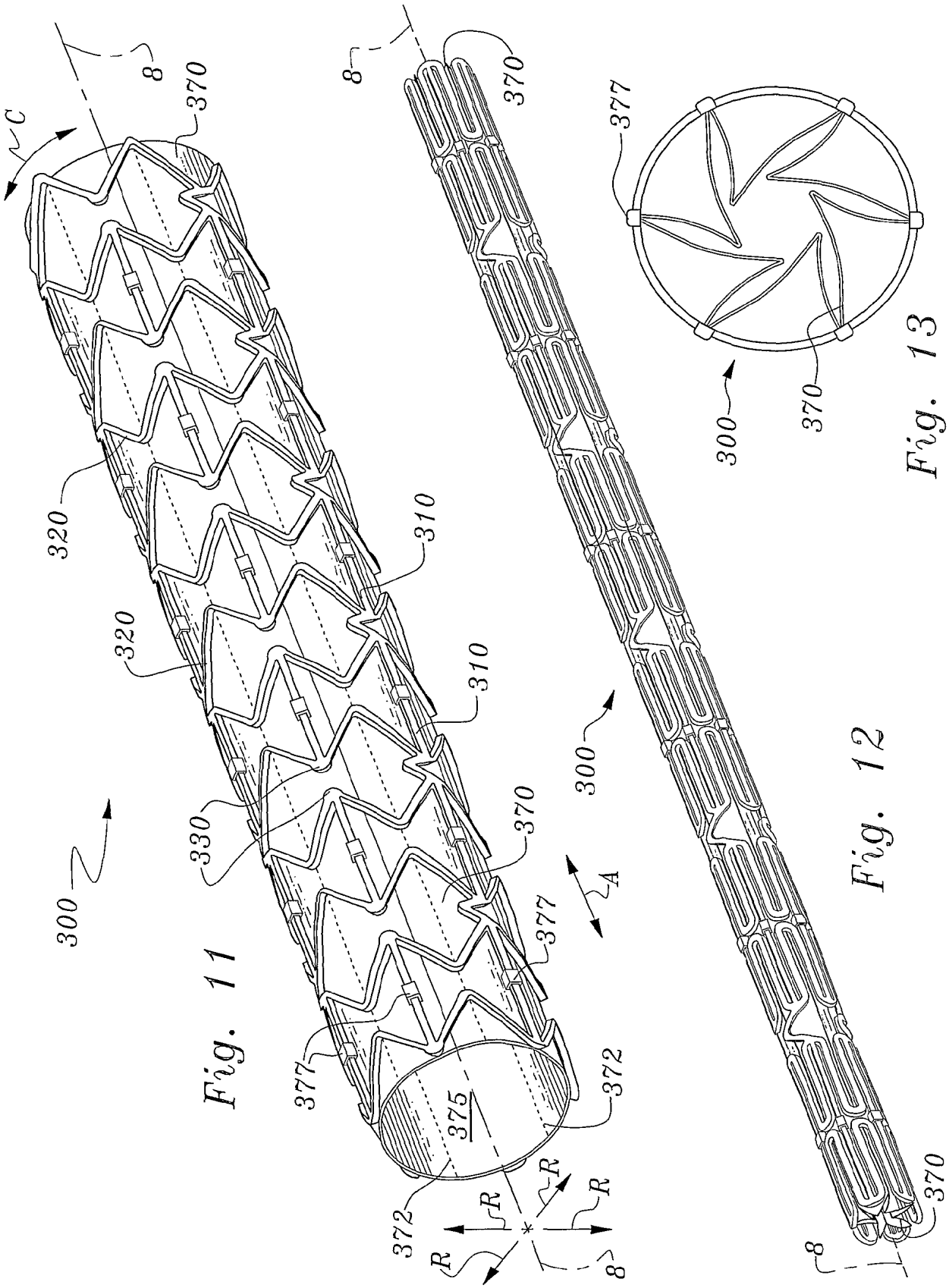

Fig. 11

Fig. 12

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/16073

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06
US CL :623/1.16
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.1, 1.16, 1.35, 1.44, 1.46, 1.47, 1.48, 1.49

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST BRS
search terms: covering, parylene, aneurysm, crotch, silicone, polycarbonate

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,824,040 A (COX et al.) 20 October 1998, figures 3A-3C.	1-3,9-16, 19-26
Y		4-8,17,18
Y	US 5,800,525 A (BACHINSKI et al.) 01 September 1998, see col. 3, lines 47-48.	5,6,17,18
Y	US 4,743,258 A (IKADA et al.) 10 May 1988, see col. 3, lines 36-37.	7
Y	US 5,863,627 A (SZYCHER et al.) 26 January 1999, see entire document.	8

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 16 JULY 2001	Date of mailing of the international search report 14 AUG 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JULIAN W. WOO Telephone No. (703) 308-0421

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